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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------|----------------------|-------------------------|------------------|
| 10/015,001 | 02/19/2002 | Ernst Tennstedt | DT-5084 | 2107 |
| 7590 06/21/2004 | | | EXAMINER | |
| SIDLEY AUSTIN BROWN & WOOD LLP | | | SNAY, JEFFREY R | |
| 875 Third Avenue | | | ART UNIT | PAPER NUMBER |
| New York, NY 10022 | | | 1743 | |
| | | | DATE MAILED: 06/21/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|
| | 10/015,001 | TENNSTEDT ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Jeffrey R. Snay | 1743 | | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tir y within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from 3, cause the application to become ABANDONE | nely filed is will be considered timely. Ithe mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | <u>_</u> . | | | | | |
| • / / | | | | | | |
| 3) Since this application is in condition for allowa | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-14 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) 1-14 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o | wn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureat* See the attached detailed Office action for a list | ts have been received. ts have been received in Applicat prity documents have been receiv nu (PCT Rule 17.2(a)). | tion No red in this National Stage | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date | 4) Interview Summar Paper No(s)/Mail D 5) Notice of Informal 6) Other: | | | | | |
| | | | | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, each of claims 1-14 are directed to a "laboratory tempering device" but fail to recite any structure by which the device can be defined. Instead, the claims recite merely a method performed by the device. Since the claims fail to recite any structure associated with the device, the scope of the claims cannot be discerned in a meaningful way.

Claim Rejections - 35 USC § 102

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Danssaert et al ('263).

The instant claims have been given the best possible consideration in light of the extent of indefiniteness, described above. As such, the instant claims appear to intend recitation of a device which includes a two dimensional array for holding samples and

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temperature controlling means by which portions of the samples within the array are subject to a temperature gradient while other portions are subject to a uniform temperature. The device enables one to ascertain the optimal temperature within the applied gradient relative to an overall desired process.

Viewed in this light, the instant claims are clearly anticipated by Danssaert et al. Danssaert et al disclose a device for determining the optimal temperature for a step in a multistep thermal cycling process. Specifically, the device comprises a plurality of two dimensional arrays, one of which arrays is subjected to a thermal gradient while the remaining arrays are subject to uniform processing temperatures. The temperature gradient is applied parallel to the rows or columns of the array. See e.g. Figure 2. Danssaert et al teach as one application the provision of the gradient array in the annealing step of a nucleic acid amplification reaction. Uniform temperature arrays are provided for the remaining steps of denaturing, extending and storing. See e.g. Figure 3 of Danssaert et al. In this manner, the device of Danssaert et al enables the selective determination of optimal temperature for the annealing step of the reaction. Furthermore, the gradient array is further provided with heating means such that the array can be operated at uniform rather than gradient temperatures (column 6, lines 39-42), and additional gradient arrays within the device are also disclosed (column 10, lines 5-12). Thus, Danssaert et al enable one of ordinary skill in the art to provide temperature gradient arrays to other steps in the reaction process while returning the annealing stage to uniform temperature. By this structure, the disclosed device would

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have been fully capable and enabled for determining the optimal temperature for each step in the amplification process.

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- 4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as general background information generally related to applicant's field of endeavor.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey R. Snay Primary Examiner Art Unit 1743